

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on May 29, 2007. No fee is due in connection with this Amendment. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-530 on the account statement.

Claims 1-5, 7-14 and 16-19 are pending in this application. Claims 6 and 15 were previously canceled. In the Office Action, Claims 1-4 and 14-19 are rejected under 35 U.S.C. §102; and Claims 5, 7-16 and 19 are rejected under 35 U.S.C. §103. In response, Claims 1 and 7 have been amended. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-3 and 14-19 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,117,905 to Higashiyama et al. ("*Higashiyama*"). Claims 1-3 and 14-19 are rejected under 35 U.S.C. §102 as anticipated by WO 99/65327 to Beudeker et al. ("*Beudeker*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Applicants have amended independent Claims 1 and 7 to recite in part, a stable oil that contains no more than 10% by weight of long-chain polyunsaturated fatty acids (LC-PUFAs) in the form of triacylglycerols. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 2, lines 12-17 and 20-24. Examples of the LC-PUFAs include arachidonic acid, dihomogammalinolenic acid, eicosapentaenoic acid or docosahexaenoic acid. Independent Claims 1 and 7 also recite, in part, one or more long-chain polyunsaturated fatty acids from a biomass obtained from the culture of a microorganism incorporated into a carrier oil.

An advantage of the present claims is that the carrier oil can directly be used to extract the long-chain polyunsaturated fatty acids from the biomass instead of using organic solvents such as hexane. In other words, the solvent which is used to extract the LC-PUFA from the biomass itself serves a useful purpose and does not have to be separated from the LC-PUFA after the extraction step. In alternative embodiments, the carrier oil can be high oleic acid sunflower oil (HOSFO), sunflower oil (SFO), soya bean oil, palm olein or a medium-chain triacylglycerol

(MCT, containing essentially triacylglycerols of saturated C₈-C₁₀ fatty acids), which are separate from the biomass oils that originate from the biomass containing the particular long-chain polyunsaturated fatty acids. The use of an oil for the extraction process means that the LC-PUFA is not contaminated with other fermentation products such as free fatty acids and phospholipids. Thus, it is not necessary to subject the oil to the purification steps which are necessary when an industrial solvent such as hexane is used. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest every element of the present claims.

Higashiyama fails to disclose or suggest a stable oil that contains no more than 10% by weight of long-chain polyunsaturated fatty acids in the form of triacylglycerides as required, in part, by Claims 1 and 7. *Higashiyama* also fails to disclose or suggest one or more long-chain polyunsaturated fatty acids from a biomass obtained from the culture of a microorganism incorporated into a carrier oil as required, in part, by Claims 1 and 7. Instead, *Higashiyama* is entirely directed to an edible oil originating from microorganisms that contains 20% by weight or more of arachidonic acid. See *Higashiyama*, column 2, lines 56-64. As arachidonic acid is a long-chain polyunsaturated fatty acid, *Higashiyama* discloses an edible oil that contains 20% by weight or more of long-chain polyunsaturated fatty acids. Moreover, *Higashiyama* does not disclose or suggest any separate carrier oil used to receive the long-chain polyunsaturated fatty acids from the biomass in accordance with the present claims.

Similarly, *Beudeker* fails to disclose or suggest a stable oil that contains no more than 10% by weight of long-chain polyunsaturated fatty acids as required, in part, by Claims 1 and 7. *Beudeker* also fails to disclose or suggest one or more long-chain polyunsaturated fatty acids in the form of triacylglycerides from a biomass obtained from the culture of a microorganism incorporated into a carrier oil as required, in part, by Claims 1 and 7. *Beudeker* is directed to a marine feed composition comprising microbially derived arachidonic acid (ARA). See *Beudeker*, page 3, line 24 to page 4, line 7. The oil comprising the ARA originates from microorganisms and contains a higher amount by weight of arachidonic acid (*i.e.*, LC-PUFAs) than that required by Claims 1 and 7. Moreover, *Beudeker* does not disclose or suggest any separate carrier oil used to receive the long-chain polyunsaturated fatty acids from the biomass in accordance with the present claims.

With respect to *Higashiyama* and *Beudeker*, the Patent Office asserts that both references disclose compositions containing no more than 10% by weight of long chain polyunsaturated fatty acids (LC-PUFAs) because both disclose fatty acids in the form of triglycerides and triglycerides are not LC-PUFAs or “acid[s] at all, rather, [] triglyceride[s] [are] tri-ester[s] of an acid with glycerol.” See, Office Action, page 2, lines 15-21 and page 4, lines 20-22. However, Applicants respectfully submit that this statement is based on a misunderstanding of the claims by the Patent Office. For example, as is now specified by the amendments to Claims 1 and 7, the stable oil of the presently claimed subject matter contains no more than 10% by weight of the long-chain polyunsaturated fatty acids in the form of triglycerides. As such, the long-chain polyunsaturated fatty acids of the presently claimed subject matter are not in the form of free LC-PUFAs, as is alleged by the Patent Office, but, rather, are in the form of triglycerides.

Applicants respectfully submit that the skilled artisan will immediately appreciate that long-chain polyunsaturated fatty acids may be found in several forms including, but not limited to, free acids, phospholipids and triglycerides. Specifically, *Beudeker* even discloses that arachidonic acid (ARA), a LC-PUFA, is often present in the form of phospholipids and that microbially derived ARA is usually in triglyceride form. See, *Beudeker*, page 3, lines 2-4 and 14-16. As such, the ARA of *Beudeker* is a LC-PUFA that is in the form of a triglyceride, not a free acid. Thus, although the definition of a “triglyceride” may recite, at least in part, “a tri-ester of an acid with glycerol,” as alleged by the Patent Office, Applicants respectfully submit that the skilled artisan will immediately appreciate that LC-PUFAs may be present in compositions in the form of triglycerides, as is the case with the present claims.

Therefore, because the stable oil of the presently claimed subject matter includes no more than 10% by weight of LC-PUFAs and because the LC-PUFAs of the presently claimed subject matter are in the form of triglycerides, Applicants respectfully submit that neither *Higashiyama* nor *Beudeker* disclose a stable oil containing no more than 10% by weight of the long-chain polyunsaturated fatty acids in the form of triglycerides as is required, in part, by the present claims.

For at least the reasons discussed above, Applicants respectfully submit that Claims 1 and 7 and Claims 2-3, 6 and 14-19 that depend from Claims 1 and 7 are novel, nonobvious and

distinguishable from the cited references. Accordingly, Applicants respectfully request that the rejections of Claims 1-3, 6 and 14-19 under 35 U.S.C. §102 be withdrawn.

In the Office Action, Claim 5 is rejected under 35 U.S.C. §103(a) as being unpatentable over *Higashiyama*. Claim 12 is rejected under 35 U.S.C. §103(a) as being unpatentable over *WO 96/21037* to Kyle (“*Kyle*”) in view of U.S. Patent No. 4,465,699 to Pagliaro et al. (“*Pagliaro*”) and *Higashiyama*. Applicants respectfully submit that the patentability of Claims 1 and 7 as previously discussed renders moot the obviousness rejections of Claims 5 and 12 that depend from independent Claims 1 and 7. In this regard, the cited art fails to teach or suggest the elements of Claims 5 and 12 in combination with the novel elements of Claims 1 and 7.

Claims 7-11, 13-16 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Kyle* in view of *Pagliaro*. Applicants respectfully disagree with and traverse this rejection for at least the reasons set forth below.

Independent Claim 7 recites, in part, bringing a carrier oil into contact with a biomass obtained from the culture of a microorganism containing one or more long-chain polyunsaturated fatty acids. According to an embodiment of the present invention, a separate carrier oil is directly used to selectively displace biomass oil (not unwanted impurities) from a milled biomass obtained from the culture of a microorganism. One or more LC-PUFAs from the biomass are incorporated into the carrier oil. This enables the separation of the oil from the biomass residue, for example, when the resulting biomass-oil slurry is squeezed in a press as an alternative to using a solvent extraction to obtain the oils. Consequently, although the pressed biomass cake still retains some oil, it has a very low content of LC-PUFA. The stable oil obtained by the claimed process is clean and does not need to be subjected to further purification in contrast to the oils obtained through the solvent extractions. In addition, the LC-PUFA is protected from oxidation by antioxidants present in the carrier oil. In contrast, Applicants respectfully submit that the cited references are deficient with respect to the present claims.

Applicants respectfully submit that the cited references fail to disclose each and every limitation of the present claims. Further, Applicants also respectfully submit that there exists no reason why the skilled artisan would combine the cited references to obtain the present claims because the cited references are directed to unrelated art and have completely different objectives. Moreover, Applicants also respectfully submit that the Patent Office is trying to

combine two cited references that have completely different objectives without any specific reason to do so other than a hindsight attempt to arrive at the Applicants' claimed invention, which the Federal Circuit has found time and again to be clearly improper.

For example, *Kyle* fails to disclose or suggest bringing a carrier oil into contact with a biomass obtained from the culture of a microorganism containing one or more long-chain polyunsaturated fatty acids as required by Claim 7. Applicants respectfully submit that *Kyle* recovers "crude fungal oil" by using conventional methods of extraction with a solvent such as hexane or supercritical fluids. See *Kyle*, page 13, lines 15-21 and page 15, lines 1-8. The extracted biomass oils are then removed from the solvent in another step to form crude oils that can be used directly or refined for administering to humans. See, *Kyle*, page 15, line 21. This is in direct contract to the present disclosure where extraction is performed using an oil, which was described in detail above and which is summarized in Table 2 of the specification at pages 9-10. *Kyle* fails to disclose any step involving bringing a carrier oil into contact with a biomass obtained from the culture of a microorganism containing one or more long-chain polyunsaturated fatty acids in accordance with Claim 7.

Further, *Kyle* also teaches away from the presently claimed subject matter by teaching the use of an oil with a higher LC-PUFA content than 10%. Specifically, *Kyle* teaches using fatty acids amount of up to about 70% and discloses the use of ARA in amounts from about 30-50%. See, *Kyle*, page 17, line 33-page 18, line 1. This is in direct contrast to the present claims, which require, in part, no more than 10% by weight of the long-chain polyunsaturated fatty acids in the form of triglycerides.

Pagliaro fails to remedy the deficiencies of *Kyle*. For example, *Pagliaro* also fails to disclose or suggest bringing a carrier oil into contact with a biomass obtained from the culture of a microorganism containing one or more long-chain polyunsaturated fatty acids as required by Claim 7. Instead, *Pagliaro* is entirely directed to a process for producing a decaffeinated vegetable material such as coffee or tea in aqueous extract or solid form, which fails to disclose each and every limitation of Claim 7. In fact, *Pagliaro* fails to disclose or suggest any type of microorganisms or microorganism containing one or more long-chain polyunsaturated fatty acids.

Further, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). This certainly applies, for example, where *Pagliaro* is directed toward the decaffeination of coffee and the removal of the material that is being extracted using an oil (e.g., caffeine) whereas the present disclosure is directed toward the use of the extracted material (e.g., biomass). Accordingly, the skilled artisan would have no reason to modify *Pagliaro* to arrive at the present claims because the present disclosure and *Pagliaro* are directed toward entirely different inventions. Similarly, *Pagliaro* focuses on the use of oil only as a transfer medium and is not a desirable commodity in its own right, see, *Pagliaro*, col. 7, line 41-col. 8, line 54, whereas *Kyle* relates to the bio-synthesis of lipids including arachidonic acid containing oils, see, *Kyle*, Abstract. As such, the skilled artisan would have no reason to combine *Pagliaro* with *Kyle* to arrive at the present claims because the references are directed to unrelated art and have completely different objectives.

For at least the reasons discussed above, the combination of *Kyle* and *Pagliaro* do not teach, suggest, or even disclose all of the elements of independent Claim 7 and Claims 8-11, 13-16 and 19 that depend from Claim 7, and thus, fail to render the claimed subject matter obvious. Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 5, 7-16 and 19 be reconsidered and the rejections be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

BELL, BOYD & LLOYD LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157
Phone No. 312-807-4204

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